K070091

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CardinalHealth

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APR 18 2007

SMDA REQUIREMENTS

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Coaxial Bone and Vertebral Body Biopsy Needle

Sponsor:	Cardinal Health 1430 Waukegan Road MPKB McGaw Park, IL 60085
Regulatory Affairs Contact:	Sharon Nichols
Telephone:	(847) 578-6610
Date Summary Prepared:	March 2007
Common Name:	Coaxial Bone and Vertebral Body Biopsy Needle
Classification:	Class II per 21CFR §876.1075
Predicate Devices:	Cardinal Health Jamshidi Coaxial Bone Biopsy Needle, (K813338) Stryker Bone and Vertebral Body Biopsy Kit (K032943)
Description:	This device can be used as a standalone device to remove a sample of bone tissue from a vertebral body or bone for diagnostic purposes using a coring, cutting or aspiration technique for diagnostic purposes as well as to provide and maintain access to the same surgical site. The access cannula sizes are 8, 11 and 13 gauge with coaxial needle of 11, 14, and 15.5 gauges. The needle lengths are 19 and 22 cm. This product is a single use, sterile prescriptive device.

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SMDA REQUIREMENTS (continued)

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Coaxial Bone and Vertebral Body Biopsy Needle

Intended Use:	This device is intended for use by a physician performing a bone or vertebral body biopsy using a coring, cutting, or aspiration technique.
Substantial Equivalence:	The Coaxial Bone and Vertebral Body Biopsy Needle is substantially equivalent to the Cardinal Health Coaxial Bone Biopsy Needle and the Stryker Bone and Vertebral Body Biopsy Kit in that the intended use and the performance attributes are equivalent.
Summary of Testing:	All materials used in the fabrication of the Coaxial Bone and Vertebral Body Biopsy Needle were evaluated through biological qualification safety tests as outlined in ISO 10993 Part-1 "Biological Evaluation of Medical Devices". These materials also were tested in accordance with industry recognized test methods and were found to be acceptable for the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Cardinal Health, Inc.
% Ms. Sharon Nichols
Regulatory Affairs Manager
1430 Waukegan Road
McGaw Park, Illinois 60085

APR 18 2007

Re: K070091
Trade/Device Name: Coaxial Bone and Vertebral Body Biopsy Needle
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: KNW
Dated: March 12, 2007
Received: March 13, 2007

Dear Ms. Nichols:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number (if known): K070091

Device Name: Coaxial Bone and Vertebral Body Biopsy Needle

Indications For Use: This device is intended for use by a physician performing a bone or vertebral body biopsy using a coring, cutting, or aspiration technique.

Prescription Use _X_ and/or Over-The Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070091